

BOARDS AND COMMISSIONS
Board of Pharmacy
(As Amended at ARRS, September 14, 2021)

201 KAR 2:360. Naloxone dispensing.

RELATES TO: KRS 217.186

STATUTORY AUTHORITY: KRS 217.186, KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.186 requires the Board of Pharmacy to promulgate administrative regulations governing dispensing of naloxone by a pharmacist pursuant to a physician-approved protocol. This administrative regulation establishes the minimum requirements for the pharmacist to be able to dispense naloxone pursuant to a physician-approval protocol.

Section 1. Certification. (1) A pharmacist desiring to achieve certification to initiate the dispensing of naloxone shall complete and submit an Application for Pharmacist Certification for Naloxone Dispensing, Form 1, with the board and provide the following:

- (a) Name;
- (b) Address;
- (c) Phone number; and
- (d) Pharmacist license number ~~;~~ and [

~~(e)] [Proof of education and training in the use and dispensing of naloxone for treatment of opioid overdose pursuant to Section 5 of this administrative regulation.]~~

(2) The board shall issue the certification to a pharmacist ~~[who meets the requirements of subsection (1) of this section]~~ within thirty (30) days of the receipt of the application.

Section 2. Procedures for Dispensing of Naloxone. A pharmacist may initiate the dispensing of naloxone under the following conditions:

- (1) The pharmacist has met the requirements of Section 1 of this administrative regulation;
- (2) The pharmacist has received his or her certification;
- (3) The pharmacist has a physician-approved protocol that meets the minimum requirements of Section 3 of this administrative regulation; and
- (4) The pharmacist documents the dispensing event in the pharmacy management system including:

(a) Documentation as required in 201 KAR 2:~~171~~170 for the dispensing of prescription medication; and

(b) Documentation that the individual receiving naloxone was provided with the required training and education pursuant to Section 4 of this administrative regulation, unless the recipient of the Naloxone is a person or agency operating a harm reduction program.

(5) A [The] pharmacist may dispense naloxone to any person or agency who provides training on the mechanism and circumstances for the administration of naloxone to the public as part of a harm reduction program, regardless of whom the ultimate user of the naloxone may be. The documentation of the dispensing of naloxone to any person or agency operating a harm reduction program shall satisfy any general documentation or recording requirements.

Section 3. Protocol Minimum Requirements. A physician-approved protocol authorizing a pharmacist to initiate the dispensing of naloxone shall contain:

- (1) Criteria for identifying persons or agencies eligible to receive naloxone under the protocol;

- (2) Naloxone products authorized to be dispensed, including:
 - (a) Name of product;
 - (b) Dose; and
 - (c) Route of administration;
- (3) Specific education to be provided to the person whom the naloxone is dispensed;
- (4) Procedures for documentation of naloxone dispensation, including procedures for notification of the physician authorizing the protocol, if desired by the physician in accordance with KRS 217.186(5)(b)3;
- (5) The length of time the protocol is in effect;
- (6) The date and signature of the physician approving the protocol; and
- (7) The names and work addresses of pharmacists authorized to initiate dispensing of naloxone under the protocol.

Section 4. Education to be Provided to Person Receiving Naloxone Prescription Under Protocol. A pharmacist dispensing naloxone to a person or agency not operating a harm reduction program shall provide verbal counseling and written educational materials~~[,]~~ appropriate to the dosage form of naloxone dispensed~~[, including:~~

- ~~(1) Risk factors of opioid overdose;~~
- ~~(2) Strategies to prevent opioid overdose;~~
- ~~(3) Signs of opioid overdose;~~
- ~~(4) Steps in responding to an overdose;~~
- ~~(5) Information on naloxone;~~
- ~~(6) Procedures for administering naloxone; and~~
- ~~(7) Proper storage and expiration of naloxone product dispensed].~~

Section 5. ~~[Pharmacist Education and Training Required for Certification. A pharmacist who applies for certification to initiate dispensing of naloxone shall have received education and training related to the safe dispensing of opioids and use of naloxone as rescue therapy for opioid overdose, including:~~

- ~~(1) Risk factors for opioid abuse and overdose;~~
- ~~(2) Opioid overdose prevention;~~
- ~~(3) Recognizing and responding to opioid overdoses;~~
- ~~(4) Indications for use of naloxone as rescue therapy;~~
- ~~(5) Contraindications for use of naloxone;~~
- ~~(6) Administration of naloxone;~~
- ~~(7) Adverse effects associated with naloxone rescue therapy;~~
- ~~(8) Identification of a patient who meets the criteria for provision of naloxone;~~
- ~~(9) Required education to provide to persons receiving naloxone;~~
- ~~(10) Required elements of protocol to initiate dispensing of naloxone; and~~
- ~~(11) Required documentation when initiating dispensing of naloxone.~~

~~Section 6.]~~ Incorporation by Reference. (1) "Application for Pharmacist Certification for Naloxone Dispensing", Form 1, 6/2021 ~~[7/2015]~~, is incorporated by reference.

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